K082230

510K SUMMARY

FEB - 3 2010

Xintec Corporation, dba, Convergent Laser Technologies
Vectra™ Family of Laser Systems and Accessories

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared:

Xintec Corporation, dba, Convergent Laser Technologies
1660 South Loop Road
Alameda, CA 94502

Phone: 510-832-2130
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Contact Person: Marilyn M. Chou, Ph.D.

Date Prepared: January 20, 2010

Name of Device and Name/Address of Sponsor:

Vectra™ Family of Laser Systems and Accessories

Xintec Corporation, dba, Convergent Laser Technologies
1660 South Loop Road
Alameda, CA 94502

Common or Usual Name:

Surgical Diode Laser Systems and Accessories

Classification Name:

Laser, Surgical Diode Laser System, 21 C.F.R. 878.4810,
Product Code GEX

Predicate Devices:

Biolitec Ceralas 980nm and 1470nm Diode Laser (510(k)#K024088; #K032863; #K050824; #K071295; #K072106; #K072682; #K073063; #K082225; #K083682; #K090164)

Convergent Laser Technologies 980nm Diode Laser and OptiLITE Accessories (510(k) #K060114; #K902871; #K910114; #K923599; #K944474; #K944965; #K944704; #K951760; #K992866), and Cynosure Smart Lipo Multiwavelength Laser (K080121)

Intended Use/Indications for Use:

The device is intended for delivery of laser light to soft tissue in the contact and non-contact mode during surgical procedures including via endoscopes. The device is generally indicated for use in incision, excision, vaporization, ablation, hemostasis or coagulation of soft tissue in ear, nose and throat and oral surgery (otolaryngology), arthroscopy, gastroenterology, general surgery, dermatology, plastic surgery, podiatry, urology, genecology, neurosurgery (peripheral nervous system), pulmonary and cardiothoracic surgery, dental applications, and endovenous occlusion of the greater saphenous vein.

The device is specifically indicated for use as follows:

Ear, Nose and Throat and Oral Surgery (Otolaryngology)

Hemostasis, incision, excision, ablation, coagulation and vaporization of tissue from the ear, nose, throat and adjacent areas including soft tissue in the oral cavity; examples include:

Removal of benign lesions from the ear, nose and throat, e.g., turbinectomy
Excision and vaporization of vocal cord nodules & polyps, e.g., tonselectomy, uvelaplasty
Incision and excision of carcinoma in situ, e.g., bronchoscopy
Ablation and vaporization of hyperkeratosis
Excision of carcinoma of the larynx
Laryngeal papillomectomy
Excision and vaporization of herpes simplex I and II
Neck dissection

Arthroscopy

Hemostasis, incision, excision, coagulation, vaporization and ablation of joint tissues during arthroscopic surgery; examples include:

Menisectomy
Synovectomy
Chondromalacia

Gastroenterology

Hemostasis, incision, excision, ablation, coagulation and vaporization of tissue in the upper and lower gastrointestinal tracts and also with endoscopic procedures; examples include:

Hemostasis of upper and lower GI bleeding
Excision and vaporization of colorectal carcinoma
Excision of polyps

General Surgery, Dermatology, Plastic Surgery and Podiatry

Excision, ablation, vaporization and photocoagulation of skin lesions, hemostasis, incision, excision, vaporization, ablation and debulking of soft tissue, abdominal, rectal, skin, fat or muscle tissue and dermabrasion; examples include:

Matrixectomy
Excision of neuromas
Excision of periungual and subungual warts
Excision of plantar warts and keloids
Liver resection
Excision of cutaneous lesions
Hemorrhoidectomy

Appendectomy
Debridement of decubitus ulcers
Hepatobiliary tumors
Mastectomy
Dermabrasion
Vaporization and hemostasis of capillary hemangioma
Excision, vaporization and hemostasis of abdominal tumors
Excision, vaporization and hemostasis of rectal pathology
Pilonidal cystectomy
Herniorapphy
Adhesiolysis
Parathyroidectomy
Laparoscopic cholecystectomy
Thyroidectomy
Resection of organs
Debridement of wounds
Photocoagulation of teleangectasia of the legs and face
Photocoagulation of vascular lesions of the face and extremities
Endovascular coagulation of the greater saphenous vein of the thigh in patients with superficial vein reflux
Treatment of reticular veins and branch varicosities

Urology

Excision, vaporization, incision, coagulation, ablation and hemostasis of urological, including BPH/prostatic, tissues; examples include:
Vaporization of uretheral tumors
Release of urethral stricture
Removal of bladder neck obstruction
Excision and vaporization of condyloma
Lesions of external genitalia
Vaporization of the prostate to treat benign prostatic hyperplasia (BPH)

Gynecology

Ablation, excision, incision, coagulation, hemostasis and vaporization of gynechological tissue; examples include:
Endometrial ablation
Excision or vaporization of condylomata acuminata
Vaporization of cervical intraepithelial neoplasia
Cervical conization
Menorrhagia

Neurosurgery

Vaporization, coagulation, excision, incision, ablation and hemostasis of soft tissue; examples include: Hemeostasis in conjunction with menigiomas

Cardiac Surgery

Hemostasis and coagulation of soft tissue, including cardiac tissue

Pulmonary Surgery

Hemostasis, vaporization, coagulation, incision, excision and ablation of soft tissue in the pulmonary system; examples include:
Tracheobronchial malignancy or stricture
Benign and malignant pulmonary obstruction
Endoscopic pulmonary applications

Dental Applications

Indicated for the following applications on intraoral and extraoral soft tissue (including marginal and interdental gingival and epithelial lining of free gingival): frenectomy, frenotomy, biopsy, operculectomy, implant recovery, gingivectomy, gingivoplasty, gingival troughing, crown lengthening, hemostasis of donor site, removal of granulation tissue, laser assisted flap surgery, debridement of diseased epithelial lining, incisions and draining of abscesses, tissue retraction for impressions, papillectomy, vestibuloplasty, excision of lesions, exposure of unerupted/partially erupted teeth, leukoplakia, removal of hyperplastic tissues, treatment of aphthous ulcers and sulcular debridement (removal of diseased or inflamed soft tissue in the periodontal pocket), pulpotomy, pulpotomy as an adjunct to root canal therapy and light activation of bleaching materials for teeth whitening.

Endovenous Occlusion of the Greater Saphenous Vein in Patients with Superficial Vein Reflux

Indicated for use in the endovascular coagulation of the Greater Saphenous Vein (GSV) of the thigh in patients with Superficial Vein Reflux associated with varicose veins and varicosities

Technological Characteristics

The Vectra Family of Laser Systems emitting 980nm and 1470 nm wavelengths are substantially equivalent to the Xintec Corporation Vectra Laser Systems (Xintec Corporation, dba, Convergent Laser Technologies, Alameda, CA) and Ceralas D 980nm and 1470nm Diode Laser Systems (East Longmeadow, MA) which have been previously cleared for marketing under applicable 510(k) pre-market notification regulations.

Performance Data

There should be no significant differences in laser delivery performance for each of 980nm and 1470nm wavelengths for the Vectra Family of Laser Systems compared to the cleared predicate devices.

Substantial Equivalence

The Vectra Family of Laser Systems are substantially equivalent to Biolitec Ceralas 980nm and 1470nm Diode Laser (510(k)#K024088; #K032863; #K050824; #K071295; #K072106; #K072682; #K073063; #K082225; #K083682; #K090164); Convergent Laser Technologies 980nm Diode Laser and OptiLITE Accessories (510(k) #K060114; #K902871; #K910114; #K923599; #K944474; #K944965; #K944704; #K951760; #K992866); and Cynosure Smart Lipo Multiwavelength Laser (K080121)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

FEB - 3 2010

Xintec Corporation
% Convergent Laser Technologies
Marilyn M. Chou, Ph.D.
1660 South Loop Road
Alameda, California 94502

Re: K082230
Trade/Device Name: Vectra™ Plus Laser System and Accessories
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: January 20, 2010
Received: January 22, 2010

Dear Dr. Chou:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: #K082230

Device Name: Vectra™ Family of Laser Systems and Accessories

The Vectra Family of Laser Systems and Accessories are indicated for ablation, vaporization, coagulation, incision/excision of soft tissue in contact or non-contact mode including open surgery and via endoscopes, introducers, trocars, or catheters. The Vectra Family of Laser Systems and Accessories are indicated for use in surgical procedures on skin, subcutaneous tissue, striated and smooth muscle, mucus membrane, lymph vessels and nodes, organs and glands in surgical specialties including but not limited to genitourinary surgery, urology (including BPH), gynecology (GYN), gastroenterology, dermatology, general surgery (including specific treatment of varicose veins, varicosities associated with superficial reflux of the greater saphenous vein, removal of pigmented lesions, photothermolysis of hair follicles), neurosurgery, otolaryngology (ENT), orthopedics, ophthalmology, podiatry, pulmonary/ thoracic surgery, dentistry and oral surgery (intra/extra oral soft tissue, e.g., removal of diseased soft tissue in the periodontal pocket, and for light activation of bleaching materials for teeth whitening.)

Intended Use/Indications for Use:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____X_____ OR Over-The-Counter Use _____

(21 CFR 801.109)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K082230